K083553

Special 510(k) Summary

A) Submitted by Schoelly Imaging, Inc
100 Hartwell St
West Boylston, MA 01583
Registration 8043903

JAN 16 2009

Contact MEDIcept
200 Homer Ave
Ashland, MA 01721
F David Rothkopf
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Date of Application November 26, 2008

B) Device Name Naso-Laryngo-Pharyngoscope

Common Name Nasopharyngoscope

Device Class 21 CFR 874 4760 CLASS II

Product Code EOB

C) Predicate Naso-Laryngo-Pharyngoscope (K991560)

D) Device Description

The Schoelly Naso-Laryngo-Pharyngoscope is a flexible and steerable fiberoptic endoscope for diagnostic purposes

E) Intended Use

The Schoelly Naso-Laryngo-Pharyngoscope is intended to be used by qualified surgeons and physicians to visualize and observe the pharynx and the larynx

F) Comparison to Predicate Device(s)

The Schoelly Naso-Laryngo-Pharyngoscope has the same intended use, target population, clinical setting, and technology as its predicate device Schoelly Naso-Laryngo-Pharyngoscope (K991560) There is no change to in compatibility with the environment or other devices, no differences in electrical, mechanical or chemical safety There are slight changes in the optical and mechanical specifications and patient contact materials, all of which have non-significant impact on device performance All changes have been made under design control, and validation was performed and conformance assured

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Features	**Schoelly Naso-Laryngoscope (the Special 510K application herein)**		**Schoelly-Naso-Laryngoscope (K991560)**
Intended Use	Visualize and observe the pharynx and the larynx		Visualize and observe the pharynx and the larynx
Design	Flexible and steerable fiberoptic endoscope for diagnostic purposes		Flexible and steerable fiberoptic endoscope for diagnostic purposes
Parts number	31 1001s	31 0001s/31 1002s	31 0001s
Specifications			
Tip tubing diameter	**3.2 mm**	**3.8 mm**[1]	**3.8 mm**
Working Length	300 mm	300 mm	300 mm
Angulation Up	140^0	120^0	150^0
Angulation Down	140^0	120^0	150^0
Direction of view	0°	0°	0°
Field of View	70^0	80^0	85°
Length of distal tip deflection	20 mm	25 mm	25 mm
Depth of field	6 – 1000 mm	6 - 1000 mm	3mm – 50mm
Total Fibers (pixels)	7,000	12,000/16,000	10,000
Fiber size	8 3 µm	7 6 µm/6 7 µm	8 3 µm
Magnification[3]	7X	9X	2 5 X
Energy used	IEC601-1 and IEC 60601-2-18 2000 compliant		
Labeling Sterilization*/Cleaning *device is supplied as non-sterile	The Instruction Manual states Sterilization Section 7 5 Flexible Schoelly endoscopes with air-exhaust valve **can** also be gas sterilized using ethylene oxide " Specifications Gas mixture 6% EtO, 94% CO_2 Temperature 131^0F+/-5^0F, 55^0C +/-2^0C Relative air humidity 40-90% Pressure (overpressure), 1 7 bar (170kpa) Exposure time 120 mins		Users Manual states "The Schoelly Naso-Laryngo-Pharyngoscope is provided non-sterile, and **must** be sterilized using EtO sterilization prior to use " Specifications EO concentration 600 +/- 25 mg/L Temperature 54+/- 2^0C (58^0C) max) Relative humidity 70% +/- 5% Pressure 14 +/- 1 PSIG

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	Cleaning Section 7 2 states " Place the endoscope and the unscrewed parts in a suitable disinfection solution (can also double up as a cleaning solution) The disinfection solution used should be permitted by the manufacturer for such use Material compatibility releases exist for the following disinfectants *Gigasept FF, Schulke & Mayr GmbH *Lysetol FF *Helipur HplusN, B Braun Medical AG *Cidex, Johnson & Johnson "	Gas exposure time 4 hours " To dissolve various impurities, use mild cleaning substances "

[1] Manufactured in two resolutions, 12,000 and 16,000 pixels

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2009

Schoelly Imaging, Inc
c/o David McNally
100 Hartwell Street
West Boylston, MA 01583

Re K083553
Trade/Device Name Naso-Pharyngoscope
Regulation Number 21 CFR 874 4760
Regulation Name Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class Class, II
Product Code EOB
Dated November 20, 2008
Received December 18, 2008

Dear Mr McNally

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www fda gov/cdrh/industry/support/index html

Sincerely yours,

M. B. Eydelman, MD

Malvina B Eydelman, M D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K083553

Indications for Use

510(k) Number (if known) K083553

Device Name Naso-Laryngo-Pharyngoscope

Indications for Use

The Schoelly Naso-Laryngo-Pharyngoscope is intended to be used by qualified surgeons and physicians to visualize and observe the pharynx and the larynx.

Prescription Use X 21CFR 801, Subpart D **OR** Over-the-Counter Use _ 21CFR 801 109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device InVitro Diagnostic Device Evaluation and Safety (OIVD)

Karen H Baker

Division Sign Off
Office of Device InVitro Diagnostic Device Evaluation and Safety

510 (K) K083553